

## DEPARTMENT OF VETERANS AFFAIRS

## Justification and Approval

For

Brand Name Only

1. **Contracting Activity:** The agency is the Veterans Health Administration (VHA), Eastern Colorado Health Care System. The contracting activity is the VHA Rocky Mountain Acquisition Center, VISN 19, 4100 E. Mississippi Avenue, Ste 900, Glendale, CO 80246. The Purchase Request Number is 554-14-3-068-0312.
2. **Nature and/or Description of the Action Being Processed:** This is a follow-on procurement and the contract contemplated will be a firm fixed price. Distributors for Synthes are American Medical Depot, 10315 USA Today Way, Miramar, FL 33025 and/or Beacon Point Associates LLC, 21001 Johnson Street, Suite 109, Pembroke Pines, FL 33029
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The requirement is to purchase for the Ortho-Spine Surgery Service from the vendor Synthes, Two upgraded Synthes Zero P sets. Presently the VA owns two complete sets of the Zero-P Synthes Spine sets that will be upgraded. It is required that the upgrades must work with and are engineered to work with the Zero-P Synthes Spine sets that the Denver VA hospital already owns. The supplies are proprietary products for a previous purchase, of the two Zero-P Synthes Spine sets that the VA owns. This set contains upgraded implants and instruments that are used during anterior/posterior cervical spinal surgery to place plates, screws and cages to fuse a cervical spine. The products required through this procurement will accommodate equipment malfunction during surgery and unexpected problems involved with the sterilization processes to accommodate a quick turnover in reprocessing the sets. A local sales representative must be available to be present in the operating room when needed during surgical cases to assist in questions from the surgeons, able to speak English and understand English. The vendor sterilization parameters must meet the guidelines of Synthes Zero P manufacturer recommendations for sterilization.  
The above Zero-P Synthes set, is required for the VA Denver Medical Center's OrthoSpine Surgery Department, for a total of \$138,532.00.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c) (1), as implemented by FAR 6.302.1

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.  
(X) (2) Unusual and Compelling Urgency per FAR 6.302-2;  
( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability

- ( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ( ) (4) International Agreement per FAR 6.302-4
- ( ) (5) Authorized or Required by Statute FAR 6.302-5;
- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7;

**5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

1) The nature of this acquisition represents a follow-on procurement of additional supplies. The proposed contractor, Synthes USA Sales LLC, is the manufacturer of the Zero P Synthes Spine Upgrade. Synthes, solely owns all proprietary rights of the system and all related instruments, and distributes through American Medical Depot and/or Beacon Point Associates. The upgrade required is designed and engineered to work only with the Zero-P Synthes Spine sets that the VA already owns.

2) This request is urgent as the Denver VA Operating Room currently does not have an upgraded set. The products required through this procurement will update the current two VA sets. Obtaining the needed implants and sets from the Synthes reps for an emergency procedure can be difficult. Sometimes the sets are not available, and sometimes having the sets available to meet the deadline by SPS to have them sterilized before surgery becomes problematic. The attached quote will upgrade the present sets to the levels they should be at with the auxiliary set. This is a proprietary set of instruments that have been designed and engineered to be used only with Zero-P Synthes Spine sets. Currently, the Denver VA owns two Zero-P Synthes spine sets that are required to be upgraded.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable** Since Synthes is the manufacturer of the instruments to be upgraded, efforts to include additional sources have been limited. The manufacturer currently uses the distributor American Medical Depot and/or Beacon Point associates. The staff physicians/surgeons are constantly surveying the professional literature and attending professional development seminars to stay abreast of any developments in this specialized field.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated total dollar amount of the proposed acquisition is \$138,532.00. Since, the Denver VA, already owns two Zero-P Synthes Spine sets that will be upgraded, an anticipated indefinite delivery/indefinite quantity contract, (using existing cost data), should create cost savings opportunities for the VHA.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research results also reveal that they are also the only source manufacturer capable of meeting the government's need for this type of capability. However, research of the marketplace is continuous and ongoing by the Ortho-Spine Surgery Program office.

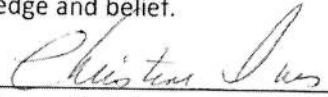
**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:** No.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.

**11. A Statement of the Actions, if any, the Agency May Take to Remove or overcome any**

**Barriers to Competition before making subsequent acquisitions for the supplies or services required:** The VHA medical staff is constantly pursuing the results of clinical trials or products under development that could offer compatibility and reduce or prevent the limitation of competition.

- 12. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

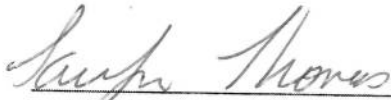


Name Christine Ives  
Title OR Manager  
Facility Denver VA ECHS VISN 19

6/2/14  
Date

**13. Approvals in accordance with FAR 6.304**

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Name  
Title  
Facility

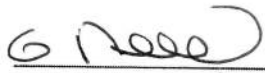
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Date

- b. **VISN/PCA QA (Required \$3K and above):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

\_\_\_\_\_  
Name  
Title  
Facility

\_\_\_\_\_  
Date

- c. **NCM/PCM (Required \$3K and above):** I certify that the justification meets requirements for other than full and open competition.

  
Name Gary Arwood  
Title Div. Chief  
Facility NCO19

6/12/2014  
Date